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*Admitted only in Maryland * Admitted only in Virginia • Practice Limited to Federal Agencies

October 13, 2004

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Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Appl. No.: 10/633,699; Filed: August 5, 2003

For: Glycosylation Engineering of Antibodies for Improving Antibody-

Dependent Cellular Cytotoxicity

Inventors:

Pablo UMAÑA et al.

Our Ref:

1975.0010004/TJS

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Information Disclosure Statement;
- 2. A listing of the cited documents on Form PTO-1449 (50 pages);
- 3. Copies of cited documents (AL1, AK1, AR45 and AS45); and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

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Commissioner for Patents October 13, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Timothy J. Shea, Jr.
Attorney for Applicants
Registration No. 41,306

TJS/AWL:ddc Enclosures

321993_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

e application of:

Pablo UMAÑA et al.

Appl. No.: 10/633,699

Filed: August 5, 2003

For: Glycosylation Engineering of

Antibodies for Improving Antibody-Dependent Cellular Cytotoxicity Confirmation No.: 5489

Art Unit: 1646

Examiner: To Be Assigned

Atty. Docket: 1975.0010004/TJS

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 (50 sheets) are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AL1, AK1, AR45, and AS45 are included.

It is brought to the Examiner's attention that document **AL1**, PCT Patent Publication No. WO 94/11026, has replaced document **AN1**, European Patent Publication No. EP 0 669 836 B1, which was submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(b)(4) in Application No. 09/294,584, filed April 20, 1999.

A copy of document AJ1 is not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/294,584, filed April 20, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter: U.S. Patent Application No. 2004/0072290 A1, Umaña *et al.*, filed May 14, 2003, published April 15, 2004 and submitted herewith as document **AK1**; and U.S. Patent Application No. 10/633,697, Umaña *et al.*, filed August 5, 2003 and submitted herewith as document **AR45**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Pablo UMAÑA et al. Appl. No. 10/633,699

- 3 -

Applicants reserve the right to establish the patentability of the claimed invention

over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the

teachings purportedly offered.

This statement should not be construed as a representation that a search has been

made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on

the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a

first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the

enclosed Form PTO-1449, and indicate in the official file wrapper of this patent

application that the documents have been considered. The U.S. Patent and Trademark

Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to

our Deposit Account No. 19-0036.

Respectfully submitted,

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Timothy J. Shea, Jr.

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Date: October 13, 2004

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(202) 371-2600

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

	ATTY. DOCKET NO. 1975.0010004/TJS	APPLICATION NO. 10/633,699				
!	APPLICANT Umaña et al.					
	FILING DATE August 5, 2003	GROUP 1646				

					August 5, 2005		1040	
	 -	1		U.S. PAT	ENT DOCUMENTS	1	T	
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	1	5,051	07/29/1980	Schroeder et al.	1		08/29/1979
	AB1	4,94	6,778	08/07/1990	Ladner et al.			01/19/1989
. <u>-</u> .	AC1	5,04	7,335	09/10/1991	Paulson et al.			12/21/1988
	AD1	5,54	7,933	08/20/1996	Lin			06/07/1995
	AE1	5,73	6,137	04/07/1998	Anderson et al.			11/03/1993
	AF1	5,77	6,456	07/07/1998	Anderson et al.			06/07/1995
	AG1	5,84	3,439	12/01/1998	Anderson et al.			06/07/1995
	AH1	5,95	2,203	09/14/1999	Withers et al.			04/11/1997
	AI1	5,95	8,403	09/28/1999	Strom et al.			07/11/1994
_	AJ1	2003	/0175884 A1	09/18/2003	Umaña et al.			08/05/2002
	AK1	2004	/0072290 A1	04/15/2004	Umaña et al.			05/14/2003
				FOREIGN P.	ATENT DOCUMENTS			
EXAMINER INITIAL		DOCU	MENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 9	4/11026	05/26/1994	WIPO			Yes No
	AM1	WO 9	5/24494	09/14/1995	WIPO			Yes No
	AN1	EP 0	669 836 B1	07/03/1996	Europe			Yes No
	A01	EP 0	752 248 A1	01/08/1997	Europe			Yes No
	AP	WO 9	7/30087	08/21/1997	WIPO			Yes No
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	AR	1		ected Against	oduction and Characteri Human Neuroblastoma,"			
	AS	1	Anderson, W.	F., "Human ge	ene therapy," <i>Nature 39</i> .	2:25-30,	Nature Pub	. Co. (1998)
	AT	1			n, J.R., "Large-Scale Conerican Association for			
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	AR	2	Bailey, J.E.	, "Toward a S	Science of Metabolic E on for the Advancement	Engineeri	ng," <i>Scienc</i> e	252:1668-	
	AS	2	Bailey, J.E., et al., "Engineering Glycosylation in Animal Cells," in New Developments and New Applications in Animal Cell Technology, Merten, O.W., et al., eds., Kluwer Academic Publishers, The Netherlands, pp.5-23 (1998)						
	AT	2	Systems in Ch Carrondo, M.	Bailey, J.E., et al., "Metabolic Engineering of N-Linked Glycoform Synthesis Systems in Chinese Hamster Ovary (CHO) Cells," in Animal Cell Technology, Carrondo, M.J.T., et al., eds., Kluwer Academic Publishers, The Netherlands,					
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	AR	3	Antibody Tra	insport and	ckinger, M.C., "A d Secretion in Mou y & Sons, Inc. (19	ise Hybridoma	teror a Cel	ganelle Mon ls," <i>Biotec</i>	oclonal hnol. Bioeng.	
	AS	3	for Monoclor	al Antibo	inson, D.K., "In F dy Production," <i>Bi</i> American Institute	iotechnol. Pi	rog.	11:1-13, Am	erican	
	AT	<u>3</u>	Bitter, G.A. 684, Academi	er, G.A., "Heterologous Gene Expression in Yeast," <i>Meth. Enzymol. 152</i> :673-Academic Press, Inc. (1987)						
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	AS	<u>4</u>	Bretscher, M 261:1280-128	.S., and Munr 1, American A	o, S., "Cholesterol an Association for the Adv	d the Go ancement	olgi Apparatu c of Science	us," <i>Science</i> (1993)	
	AT	<u>4</u>	Chinese Hamst J. Biol. Cher	Briles, E.B., et al., "Isolation of Wheat Germ Agglutinin-resistant Clones of Chinese Hamster Ovary Cells Deficient in Membrane Sialic Acid and Galactose," J. Biol. Chem. 252:1107-1116, American Society for Biochemistry and Molecular Biology, Inc. (1977)					
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					ATTY. DOCKET NO. 1975.0010004/TJS		APPLICATION 10/633,699	NO.
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	AS	<u>6</u>	Caruthers, M.H., et al., "New chemical methods for synthesizing polynucleotides," Nuc. Acids Res. Symp. Series 7:215-223, IRL Press Limited (1980)					
	AT	<u>6</u>	Chow, F., et al., "Synthesis of oligodeoxyribonucleotides on silica del support," <i>Nuc. Acids Res.</i> 9:2807-2817, IRL Press Limited (1981)					
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	AR	8	Cote, R.J.,	et al., "Gene igens," <i>Proc</i>	eration of human monoclo	onal an	tibodies read	ctive with nal Academy	
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	AT	<u>8</u>	Creighton, T and Co., New	Creighton, T.E., <i>Proteins: Structures and Molecular Principles</i> , W.H. Freeman and Co., New York, NY, pp.34-60 (1983)					
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				<u></u> .	ATTY. DOCKET NO. 1975.0010004/TJS		APPLICATION 10/633,699	NO.	
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	AS	<u>9</u>	Neuroblastoma	a. Targeting	Clinical Results with g Features and Biodist ernational (1993)	the Chi	meric Antiboo Data," <i>Eur</i> .	dy chCE7 in J. Nucl.	
	АТ	<u>9</u>	Directly Asso	Dennis, J.W., et al., "β1-6 Branching of Asn-Linked Oligosaccharides Is Directly Associated with Metastasis," <i>Science 236</i> :582-585, American Association For the Advancement of Science (1987)					
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					ATTY. DOCKET NO. 1975.0010004/TJS		APPLICATION 10/633,699	
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